REMARKS

Obviousness Rejection

On page 2 of the Office Action, in paragraph 6, claims 1, 5, 7, 9, 11-13 and 19-25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ueno et al. (U.S. Patent No. 5,234,954), in view of Dietz (Pediatrics, Vol. 101, Issue 3 (Supplement), pages 518-525).

In response, Applicant submits that the disclosure at col. 18, Table 1 and lines 39-40 in Ueno et al. indicates that almost no influence was observed with respect to body weight in Test Example 1 (the only test example which discusses body weight). Accordingly, Applicant submits that the claimed method involving reducing body weight would not have been obvious from the cited art.

Applicant notes that the above argument was presented in the paragraph bridging pages 19-20 in the Amendment filed July 2, 2009, but the Examiner did not specifically respond to this argument in the present Office Action, so Applicant respectfully requests the Examiner's specific consideration of this argument, as well as the Examiner's specific response to this argument.

Moreover, Applicant submits that one of ordinary skill in the art would not have expected that a drug effective for hyperlipidemia would naturally improve a disease to which the hyperlipidemia is attributed.

In this regard, Applicant notes that as shown in the document attached hereto (Pediatr. Nephrol 1993 Oct: 7(5): 559-66 (Abstract)), hyperlipidemia is a representative characteristic in nephrotic syndrome (NS). In NS patients, the kidney is damaged, and therefore, a large amount of protein leaks from blood into urine. The reduced nutrition in the blood stimulates protein synthesis in the liver, resulting in the overproduction of lipoprotein. When the patient recovers from NS, i.e., the damaged kidney is recovered and the urinal protein disappears, the

hyperlipidemia in the patient is also improved accordingly. The hyperlipidemia associated with NS can be treated by an anti-hyperlipidemia agent. However, the anti-hyperlipidemia agent just lowers the blood lipid and/or lipoprotein and does not affect the NS or urinal protein.

In the same manner as the above, one of ordinary skill in the art would not have expected that a drug effective for hyperlipidemia would naturally improve obesity.

From the disclosure at col. 18, Table 1 and lines 39-40 in Ueno et al. and the expectation, based on the general technical knowledge in the art, that a drug effective for hyperlipidemia would not naturally improve obesity, it is apparent that one of ordinarily skill in the art would not have had a reasonable expectation of success in producing the claimed invention at the filing date of the present invention.

Moreover, Applicant submits that with respect to method of treatment claims, the relevant case law includes *Jansen v. Rexall Sundown, Inc.*, 342.F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003), wherein in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. See MPEP 2111.02 II.

Thus, Applicant submits that the present claims should be properly interpreted to mean that the recited compound must be administered to a subject with a recognized need to reduce body weight and for the purpose of reducing the body weight of that subject.

Further in this regard, Applicant submits that the cited art does not disclose or suggest administering the recited compound to a subject with a recognized need to reduce body weight

and for the purpose of reducing the body weight of that subject, and thus the cited art does not render the present invention obvious in view of the holding in *Jansen*.

Accordingly, Applicant submits that the present invention is not obvious over the cited art, and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: February 16, 2010

Pediatr Nephrol. 1993 Oct;7(5):559-66.

Hyperlipidemia in childhood nephrotic syndrome.

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Hyperlipidemia is an important characteristic of nephrotic syndrome (NS). Elevation of plasma total cholesterol, or more specifically low-density lipoprotein cholesterol, is the major lipid abnormality in NS, although hypertriglyceridemia may develop as the disorder progresses. The pathophysiology of nephrotic hyperlipidemia is complex. The prevailing view is that both hepatic synthesis of lipids and of apolipoproteins is increased, and that the clearance of chylomicrons and very low-density lipoproteins is reduced. The precise contribution of increased lipogenesis and decreased lipid catabolism to hyperlipidemia, and their relationship to urinary protein loss, hypoalbuminemia and reduced serum oncotic pressure remain controversial. There are two potential risks of elevated plasma lipids: atherosclerosis and progression of glomerular injury. Although neither of these complications has been proved with certainty, there is growing evidence that both may be long-term consequences of NS. Therefore, the diagnosis and treatment of lipid abnormalities, important aspects of the management of nephrotic children, is summarized here to provide pediatric nephrologists with an informed choice.

PMID: 8251323 [PubMed - indexed for MEDLINE]